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APPLICATION NO.	FI	LING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/759,746	01/16/2004		Ester Fernandez-Salas	ALLE0014-104 (17355CIP4)		
51957	7590	10/03/2006		EXAM	INER	
ALLERGA 2525 DUPO	•	F T2-7H	WANG, CI	WANG, CHANG YU		
IRVINE, C		•	ART UNIT	PAPER NUMBER		
				1649	1649	

DATE MAILED: 10/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)					
	10/759,746	FERNANDEZ-SALAS ET AL.					
Office Action Summary	Examiner	Art Unit					
	Chang-Yu Wang	1649					
The MAILING DATE of this communication app Period for Reply	pears on the cover sheet with the c	correspondence address					
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period of Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tir will apply and will expire SIX (6) MONTHS from , cause the application to become ABANDONE	N. nely filed the mailing date of this communication. ED (35 U.S.C. § 133).					
Status							
1) Responsive to communication(s) filed on 24 Ju	ıly 2006.						
,	action is non-final.						
•							
closed in accordance with the practice under E	Ex parte Quayle, 1935 C.D. 11, 4	53 O.G. 213.					
Disposition of Claims							
4)⊠ Claim(s) <u>1,3-22,45-47,56 and 57</u> is/are pending in the application.							
4a) Of the above claim(s) is/are withdrawn from consideration.							
5) Claim(s) is/are allowed.							
6)⊠ Claim(s) <u>1,3-22,45-47,56 and 57</u> is/are rejected.							
7) Claim(s) is/are objected to.							
8) Claim(s) are subject to restriction and/o	r election requirement.						
Application Papers							
9) The specification is objected to by the Examine	er.	·					
10)⊠ The drawing(s) filed on <u>1/16/04</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority under 35 U.S.C. § 119							
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority application from the International Bureau * See the attached detailed Office action for a list	. s have been received. s have been received in Applicat rity documents have been receiv u (PCT Rule 17.2(a)).	ion No ed in this National Stage					
Attachment(s)							
1) Notice of References Cited (PTO-892)	4) Interview Summary	(PTO-413)					
Notice of Praftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date	Paper No(s)/Mail D						

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DETAILED ACTION

RESPONSE TO AMENDMENT

Status of Application/Amendments/claims

Applicant's amendment filed July 24, 2006 is acknowledged. Claims 2, 21, 23-44 and 48-55 are cancelled. Claims 1, 3-22, 45-47 and newly added claims 56 and 57 are pending in this application and under examination in light of BoNT/A light chain. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Specification

The objection to the specification as containing an embedded hyperlink is withdrawn in response to Applicant's amendment to the specification.

Priority

The amendment to the 1st paragraph of the specification is objected to because Applicant fails to claim the relationship between the instant application and copending application 10/757,077.

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. [1] as follows:

If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 120, a specific reference to the prior-filed application in compliance with

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37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under

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37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

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The disclosures of the prior-filed applications, Application No. 10/163106, Application No. 09/910346, and Application No. 09/620840 fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The instant application claims a method of identifying a compound that alters a biological persistence of a Clostridial toxin comprising a test localization assay which is not presented in the Application Nos. 10/163106 filed on Jun 4, 2000, 09/910346 filed on Jul 20, 2001, 09/620840 filed on Jul 21, 2000. Therefore, the priority for the instant application is Jan 16, 2004.

Claim Rejections/Objections Withdrawn

The objection to claims 25 and 31 is moot because the claims are canceled.

The objection to claims 17, 18 and 47 is withdrawn in response to Applicant's amendment to the claims.

The rejection of claims 1-44 under 35 U.S.C. 112, first paragraph because the specification is not enabling the invention commensurate in scope with the claims is withdrawn in response to Applicant's amendment to the claims and cancellation of claims 2, 21, 23-44 and 48.

The rejection of claims 1-48 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in response to Applicant's amendment to the claims and cancellation of claims 2, 21, 23-44 and 48.

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The rejection of claims 1-48 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps is withdrawn in response to Applicant's amendment to the claims and cancellation of claims 2, 21, 23-44 and 48.

The rejection of claims 1-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite because of the recitation of "alter" is withdrawn in response to Applicant's amendment to the claims and cancellation of claims 2, 21, 23-44 and 48.

The rejection of claim 4 under 35 U.S.C. 112, second paragraph, as being indefinite because of the recitation of "less" is withdrawn in response to Applicant's amendment to the claim.

The rejection of claim 11 under 35 U.S.C. 112, second paragraph, as being indefinite because of the recitation of "effective amount" without further limitation is withdrawn in response to Applicant's amendment to the claim.

The rejection of claims 22 and 32 under 35 U.S.C. 112, second paragraph, as being indefinite because of the recitation of "GFP-SNAP" without limiting which SNAP is intended to include is withdrawn in response to Applicant's remarks.

The rejection of claims 16- 22 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in response to Applicant's remarks.

The provisional rejection of claims 2, 21, 23-44 and 48 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 60 of copending Application No. 10732703 ('703) in view of Herreros

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et al. (Mol. Biol. Cell. 2001. 12: 2947-2960) is moot because the claims are canceled.

The rejection of claims 23-32 under 35 U.S.C. 102 (b) as being anticipated by US Patent No. 5965699 (Schmidt et al. issued on Oct 12, 1999, effective filing date Nov 6, 1996) is moot because the claims are canceled.

The rejection of claims 23-32 under 35 U.S.C. 102 (e) as being anticipated by US Patent No. 6762280 (Schmidt et al. issued on Jul 13, 2004, effective filing date Sep 25, 2000) is most because the claims are canceled.

The provisional rejection of claims 1-48 under 35 U.S.C. 103(a) as being obvious over copending Application No. 10732703 (US20050129677) in view of Herreros et al. (Mol. Biol. Cell. 2001. 12: 2947-2960) is withdrawn in response to Applicant's showing that the copending application 10732703 and instant applicant are common owned by Allergan Inc. at the time the inventions were invented.

Claim Rejections/Objections Maintained Claim Rejections - 35 USC § 112

The rejection of claims 45-47 under 35 U.S.C. 112, first paragraph because the specification is not enabling the invention commensurate in scope with the claims is maintained for reasons of record in the previous office action. The rejection is also applied to newly added claim 57.

Applicant argues that the amended claims are enabling because the specification provides sufficient guidance to screen for compounds that affect

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localization of BoNT/A. Applicant's arguments have been fully considered but they are not found persuasive. The claims 45-47 and 57 are directed to a method of screening for a compound that reduces or increases a biological persistence of a Clostridal toxin by observing the change of localization of BoNT/A light chain on the plasma membrane. The instant specification is not enabling for identifying compounds that increase or decrease a biological persistence of all Clostridial toxins by evaluating the localization of BoNT/A light chain. A light chain of toxin is responsible for proteolytic activity, which is also responsible for interaction with substrates and the change of location of a toxin because the localization of substrate and toxin would change once the toxin binds to a substrate, such as SNAP25 or other known SNARE proteins. However, a toxin is composed of both light and heavy chains. The light chain is responsible for intracellular catalytic activity to block neuroexocytosis and heavy chain is responsible for membrane translocation and neurospecific binding (see p. 555, the second paragraph to p. ·557. Johnson Annu. Rev. Microbiol. 1999. 53:551-75, as cited in the previous office action). In addition, there are several different types of Clostridial toxins. Applicant fails to teach whether other Clostridial toxins function the same as BoNT/A. Thus, it is unpredictable whether a compound increases/decreases intracellular localization of BoNT/A would increase/decrease a biological persistence of all Clostridial toxins, indicating that undue experimentation is required for those skilled in the art to practice the claimed invention. Therefore, in view of the necessity of experimentation, the limited working examples, the unpredictability of the art, and the lack of sufficient guidance in the specification,

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one of skill in the art would be required to perform undue experimentation in order to practice the claimed invention as it pertains to a method of identifying a compound that decreases/increases a biological persistence of a Clostridial toxin by contacting the cells expressing a light chain of BoNT/A and evaluating the localization, enzyme activity of the light chain of BoNT/A. Thus, the rejection of claims 45-47 and 57 under 35 U.S.C. 112, first paragraph because the specification is not enabling the invention commensurate in scope with the claims is maintained.

Obviousness-Type Non-Statutory Double Patenting

The provisional rejection of claims 1, 3-20, 22 and 45-47 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 60 of copending Application No. 10732703 ('703) in view of Herreros et al. (Mol. Biol. Cell. 2001. 12: 2947-2960) is maintained. The rejection is also applied to new claims 56 and 57.

Applicant states to defer responding to the rejection until allowable subject matter is indicated. Applicant's arguments have been fully considered but they are not found persuasive. The rejection of claims under obviousness double patenting as being unpatentable over claims claim 60 of copending Application No. 10732703 ('703) in view of Herreros et al. (Mol. Biol. Cell. 2001. 12: 2947-2960) is maintained of record until a terminal disclaimer is filed. It is noted that traversal at the time of indication of allowable subject matter will not be considered timely. The rejection is also applied to new claims 56 and 57.

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Claim Rejections - 35 USC § 103

The rejection of claims 1, 3-20, 22 and 45-47 under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6762280 (Schmidt et al. issued on Jul 13, 2004, effective filing date Sep 25, 2000) in view of Fernandez-Salas et al. (Society for Neuroscience Abstract Viewer and Itinerary Planner, 2003. Vol 2003, pp. Abstract No. 9.2.) or Steward et al. (Naunyn-Schmiedeberg's Archives of Pharmacology, (June 2002) Vol. 365 No. Supplement 2, pp. R19) is maintained for reasons of record in the previous office action. The rejection is also applied to new claims 56 and 57.

Applicant argues that the references of US Patent No. 6762280 (Schmidt et al.), Fernandez-Salas et al.(Fernandez-Salas I), Steward et al. (Fernandez-Salas II) provide no suggestion/teaching or motivation that would lead a skilled artisan to make the claimed invention. Applicant argues that US6762280 (Schmidt et al.) does not membrane localization of BoNT/A and any sequence responsible for the localization. Applicant argues that the screening method disclosed in the reference of Schmidt et al. is for identifying a compound that alters proteolytic activity rather than biological persistence of BoNT/A because the biological persistence implies a time period that a BoNT/A is proteolytic active. Applicant also argues that Schmidt et al. does not teach a cell-based system to screen for a compound. Applicant acknowledges that Fernandes-Salas I abstract and Fernandes-Salas II do teach a correlation Applicant argues that Fernandes-Salas I abstract and Fernandes-Salas II do not teach specific

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sequence or length of sequence responsible for biological persistence of BoNT/A. Applicant argues that Fernandes-Salas I abstract and Fernandes-Salas II abstract do not teach a cell-base screening system. Applicant acknowledges that Fernandes-Salas I abstract and Fernandes-Salas II abstract do teach a correlation between the localization and a Clostridial toxin and the duration of biological persistence and the localization is mediated by signals in N- and C-termini.

Applicant's arguments have been fully considered but they are not found persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., sequences responsible for localization) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to

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do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, US Patent No. 6762280 ('280) teaches a method for identifying a compound that inhibits/enhances the proteolytic activity of botulinum neurotoxin serotype A (BoNT/A) by incubating neurotoxin with the test compound and a fluorescence labeled substrate, and measuring the fluorescence signal resulting from proteolytic cleavage of the substrate by neurotoxin. '280 teaches using an FRET assay of detecting the proteolytic activity of the light chain of BoNT/A and a ELISA method to screen a compound that inhibits/enhances the proetolytic activity of the light chain of BoNT/A. The teachings of '280 meet the limitations of screening for a compound that reduces/increases a biological persistence of BoNT/A by detecting the proteolytic activity of BoNT/A light chain on SNAP25 or other substrates of SNARE proteins. Fernandez-Salas et al. teach that the fusion protein of the light chain of BoNT/A to GFP protein is colocalized with SNAP25 when transfected in neurons. The colocalization can be detected by confocal microscopy. The teachings of Sernandez-Salas et al. meet the limitations of observing the change of localization of light chain of BoNT/A while cleaves SNAP25 since cleavage occurs in intracellular compartment and the interaction of BoNT/A light chain with SNAP25 triggers the endocytosis of the complex. Thus, it would have been obvious for one of ordinary skill in the art at the time of the instant invention was made to be motivated and have reasonable expectations of success in

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combining the teachings of US Patent No. 6762280 and Fernadez-Salas et al. to screen a compound that affects a biological persistence of a Clostridial toxin by evaluating the localization and enzymatic activity. The biological persistence of proteolytic activity of BoNT/A relies on the proteolytic activity of the light chain. In addition, the interaction of BoNT/A with its substrate, such as SNAP25, occurs intracellularly because the interaction of BoNT/A triggers the internalization of the complex and subsequently cleaves SNAP25 and inhibits exocytosis of synaptic vesicles. Therefore, one of ordinary skill in the art would have expected success in screening a compound that reduces/increases a biological persistence of a BoNT/A by contacting cells expressing a light chain of BoNT/A with test compounds and evaluating the localization and proteolytic activity of the BoNT/A light chain on SNAP25. Thus, the rejection of claims 1, 3-20, 22 and 45-47 under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6762280 (Schmidt et al. issued on Jul 13, 2004, effective filing date Sep 25, 2000) in view of Fernandez-Salas et al. (Society for Neuroscience Abstract Viewer and Itinerary Planner, 2003, Vol 2003, pp. Abstract No. 9.2.) or Steward et al. (Naunyn-Schmiedeberg's Archives of Pharmacology, (June 2002) Vol. 365 No. Supplement 2, pp. R19) is maintained.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

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person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 4, 46 and 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claims as amended are directed to a method of identifying a compound that either reduces or increases a biological persistence of a BoNT/A or a Clostridial toxin comprising comparing the effects of the test compound that increased about 20% to about 300% more BoNT/A light chain localized on the plasma membrane or reduced about 10% to about 90% reduction on plasma membrane. The instant claims now recite limitations of about 20% to about 300% increase and about 10% to about 90% reduction, which were not clearly disclosed in the specification and claims as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in the present claims, which did not appear in the specification or original claims, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant fails to disclose <u>about 20% to about 300% increase</u> as recited in claims 3 and 46, and <u>about 10% to about 90% reduction</u> as recited in claims 4 and 47. The specification fails to disclose the limitations for the percentages of

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increase or reduction. Applicant only discloses "the density of the light chain of toxin type A that is localized to the plasma membrane is reduced by more than about 20%, preferably more than about 40%, more preferably more than about 60%, for example 80%" (see p. 31 in the specification). Applicant provides no guidance as to how much percentages of change would be considered as about 20% to about 300% increase or about 20% to about 90% reduction since the scope of the range of increase or reduction in the amended claims is different from the original disclosures. Accordingly, in the absence of sufficient recitation of the range of percentages, the specification does not provide adequate written description to support about 20% to about 300% increase as recited in claims 3 and 46, and about 10% to about 90% reduction as recited in claims 4 and 47. Support is not found for the limitations of about 20% to about 300% increase and about 10% to about 90% reduction as disclosed in the original specification and thus the recitations constitute new matter absent evidence for their support. Applicant is required to cancel the new matter in the reply to this office action. Alternatively, Applicant is invited to clearly point out the written support for the

Conclusion

NO CLAIM IS ALLOWED.

instant limitations.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL.

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See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang, Ph.D. whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Thursday and every other Friday from 8:30 AM to 5:30 PM. If attempts to reach

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the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D., can be reached at (571) 272-0867.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CYW September 27, 2006

JANET L. ANDRÉS
SUPERVISORY PATENT EXAMINER

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